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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,093	11/24/1999	DOV HARTAL	4118	5856

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EXAMINER

SHERRER, CURTIS EDWARD

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 12/18/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/449,093

Applicant(s)
Hartal et al.

Examiner
Curtis E. Sherrer

Art Unit
1761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 26, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 23-28, and 41-45 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 23-28, and 41-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: |

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Part III DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-14, 23-28, 44 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
2. Applicants directed the examiner's attention to page 9, line of the instant specification but this only provides a basis for the concentration of lycopene rather than the "coloring material." While applicants state that it "will be understood that . . . the concentration . . . is for the lycopene-encapsulated material . . ." no support for this statement is given.
3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 1-14, 23-28 and 41-45 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Applicants state that processing steps are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).
5. Applicants cite to their specification whereby it states "conventional methods of extraction destroy the crystalline structure of this pigment." They state that a "key aspect of the present

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invention therefor is to liberate the chromoplast from the fruit without causing substantial mechanical breakage or destruction of the chromoplast." Page 9 of Paper #9, After Final Amendment). A review of the specification discloses that the processing of tomatoes to produce the instant product (except for the centrifugation) is "not essentially different [than] those conventionally carried out in the tomato processing industry." It is therefore unclear, at present, what process conditions (extraction steps) are being relied on to keep the chromoplast particles intact.

In response to this rejection, applicants state that the disclosed centrifugation works sufficiently to produce the claimed invention. This statement alone does not overcome the rejection. If centrifugation is the only disclosed known method of obtaining the claimed invention, then it should be in the independent claims. Further, applicants do not elucidate on what might have been well known at the time of invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-14, 23-28 and 41-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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8. Claim 5 is indefinite because the scope of the phrase "high lycopene content tomato" is unknown. Applicants respond by stating that said tomatoes are well known but provide no support for such a statement.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

10. Claims 1-14, 23-25, 28 and 45 to are rejected under 35 U.S.C. § 102(b)/102(e) as being anticipated by Graves et al (USPN 5,245,095) for the reasons set forth in the last Office Action.

11. Claims 14, and 41-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by Tannuci et al (Jnl. of Agricultural and Food Chemistry) for the reasons set forth in the last Office Action.

12. Claims 1-3, 5 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Iwatsuki et al. (Plant Cell Physiology, Abstract) for the reasons set forth in the last Office Action.

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13. Claims 8, 9 and 11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Dale et al. (Jnl. of Food Sci.) for the reasons set forth in the last Office Action.

14. Claims 1-3 and 5-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Brumlick et al. (U.S. Pat. No. 4,181,743) for the reasons set forth in the last Office Action.

15. Claims 1-3, 5, 6, 13, and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Szabo et al. (U.S. Pat. No. 3,864,504) for the reasons set forth in the last Office Action.

16. Claims 1-5 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bradley (U.S. Pat. No. 4,670,281) for the reasons set forth in the last Office Action.

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

18. Claims 1-5, 7 and 13 and 14 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lang (U.S. Pat. No. 5,229,160) for the reasons set forth in the last Office Action.

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Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 26 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Graves et al. in view of Horn et al (U.S. Pat. No. 4,726,955) for the reasons set forth in the last Office Action.

21. Claims 1-5, 7, 13 and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lang in view of Brumlick et al.) for the reasons set forth in the last Office Action.

22. Claims 1-14, 24-28 and 45 are rejected under 35 U.S.C. § 103 as being unpatentable Tannuci et al (Jnl. of Agricultural and Food Chemistry) in view of Dale et al. (Jnl. of Food Sci) for the reasons set forth in the last Office Action.

Response to Arguments

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23. Applicants' arguments filed 01/02/02 have been fully considered but they are not persuasive.

24. Applicants argue that Graves does not anticipate the rejected claims because Graves works with the liquid fraction. In response, it is noted that the instant claims are not restricted to non-liquid fractions. Applicants also state that Graves teaches the disruption of the cells of the carotenoid source. The importance of this teaching is not understood. It does not state that the carotenoid cells are disrupted but that the cells from where the carotenoids are obtained are disrupted. Further, the process claims require the removal of solids, and this is the same as done by Graves. No difference could be found between the teachings of Graves and the rejected claims.

25. Applicant argues that Tonnuci does not anticipate the product claims because the tested products would have had the chromoplasts destroyed due to the heat that occurs to commercially available products. Applicants claims do not exclude heating the final product and therefore it is considered that the Tonnuci products are the same, either before or after the asserted heating step.

26. Applicants argue that Iwatsuki is a non-enabling reference because applicants do not understand the teaching found under the Results and Discussion section relating to gelling. It appear that the authors were merely stating that if one wants to avoid gelling a homogenate, then

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if must be run through the Sephadex column. This prevents the homogenates from gelling. It is not considered that Iwatsuki is non-enabling and therefore the rejection is maintained.

Applicants assert that, because Dale heats the chopped tomatoes, that this goes against applicants invention. First, the claims do not literally exclude heating the tomato solids. Second, applicants do not rely on any evidence to show that the heating of Dale would destroy the chromoplast structure.

27. Applicants then states that Brumlick is non-enabling because the liquid rather than the solid fraction is worked with. As stated above, applicants also work with a liquid phase. Certainly applicants do not centrifuge a solid phase. Applicant also seem to ignore that Brumlick refers to freeze drying as an alternative to heating.

28. Applicants state that the product of Szabo "is inevitably heated to a relatively high temperature which inevitably results in the destruction of chromoplasts." "Presumably evaporation involves substantial heat." No basis for these presumptions is provided. Applicants also state that the present invention has neither a tomato smell or taste. As yet, the claims are not so limited.

29. Applicants argue that Bradley and Lang heat their tomato material and therefore, as argued above, the chromoplast would be degraded. Again, applicants have provided no evidence as to what temperatures degrade chromoplast. Applicants compare the fruit cell to the chromoplast and nothing on the record indicates that they have equivalent structures or chemical properties.

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30. With regard to the obviousness rejections, applicants argue that the secondary references to not make up for the deficiencies of the primary reference and therefore rejections are improper. It is respectfully considered that the rejections meet all the limitations of the claims and therefore a *prima facie* case of obviousness exists.

31. Again, the Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed are functionally different than those taught by the prior art and to establish patentable differences. See *In re Best*, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 1977); *Ex parte Gray*, 10 U.S.P.Q.2d 1922, 1923 (BPAI).

Conclusion

32. No claim is allowed.

33. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

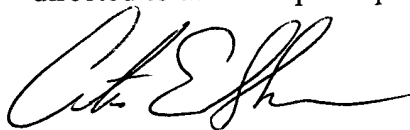
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Curtis Sherrer whose telephone number is (703) 308-3847. The examiner can normally be reached on Tuesday through Friday from 6:30 to 4:30. The fax phone number for this Group is (703)-305-3602.

35. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.



Curtis E. Sherrer
Primary Examiner
December 17, 2002